



# Pesticide Registration Service Fees

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# Pesticide Registration Service Fees

- Overview of Pesticide Registration Improvement Act of 2003 -

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# Wide participation in fees workgroup

- EPA
- CLA / RISE
- CSPA
- CPDA
- ACC
- Biopesticide Industry
- NRDC
- Consumers Union
- Protected Harvest

# Benefits of proposed Bill

- Reduced timeframes for registration decisions
- Greater predictability for registration decisions
- More accountability for registration decisions
- Enhanced resources to assure that FQPA and reregistration deadlines are achieved
- More stable, predictable and augmented funding for pesticide program

# Overview: Maintenance Fees

- \$116M to be collected over 5 years
  - Front-end loaded
- Caps increased so fees are more equitably spread across various pesticide industry sectors
- Approximately \$3M earmarked for fast tracks & new inert reviews

# Overview: Enhanced Registration Service fees

- Generates \$15M - \$20M per year
- Fees increased 5% after 2 years but no COLA
- Protection of FY02 funding level for OPP
- Fees tied to specific decision completion timeframes; completion timeframes are gradually reduced
- Shorter timeframes for reduced-risk
- Judicial review for new AIs & new uses where completion timeframe is exceeded by more than 2 years

# Overview: Enhanced Registration Service Fees

- Fee waiver provisions for small businesses, minor uses, IR-4 and state & federal agencies
- \$1M per year earmarked for worker exposure activities
- Increased transparency provided by annual auditing and reporting requirements
- New hires exempted from agency-wide FTE ceiling



# Registration Requirements for Antimicrobial Pesticides

- Timeframes for amendments requiring scientific review reduced to 120 days
- Failure to make decision in the reduced timeframe no longer judicially reviewable



# Maintenance Fees

- Caps adjusted so fees are more equitably spread across various pesticide industry sectors
- Maintenance fees increased and front-loaded:
  - FY04 - \$26M
  - FY05 - \$27M
  - FY06 - \$27M
  - FY07 - \$21M
  - FY08 - \$15M

# Small Business Definition Updated

- Increases employee cap from 150 to 500
- Increases average annual gross global revenues from \$40M to \$60M
- Provides language to tighten loopholes for “affiliates”, “affiliated persons” and “indicia of control”

## Reregistration and Other Activities

- Requires all food-use REDs be completed by August 3, 2006
- Requires all non-food-use REDs be completed by October 3, 2008
- Gives 2 additional years for data required in the RED to be submitted before product reregistration decision

## Other Fees

- Cannot levy other registration fees
- Suspends authority to collect the tolerance petition fee through September 30, 2008

# Expedited Processing of Similar Applications

- Earmark includes review of new inert ingredients as well as fast tracks
- Increases amount of maintenance fees earmarked for fast tracks & inerts:
  - FY04 - \$3.3M
  - FY05 - \$3.3M
  - FY06 - \$3.3M
  - FY07 - \$2.6M - \$3.0M
  - FY08 - \$1.9M - \$2.1M

# Pesticide Registration Service Fees

- Defines costs that fees can be used for to include:
  1. OPP management & staff directly involved in review of covered pesticide applications
  2. Contractors that are directly involved in review of covered pesticide applications
  3. Advisory committees that engage in peer reviews of covered pesticide applications
  4. Information management costs associated with reviews of covered pesticide applications
  5. Costs of collecting fees, tracking fees, reporting and auditing

# Fees

- Fees are required for all covered pesticide applications submitted on or after the effective date
- All currently pending new AI applications must pay fee except those that are carried over from RD's FY03 Workplan
- Fees for pending applications are reduced by amount of previously paid tolerance fees



# Fees

- Applications submitted on or after March 23, 2004 must include documentation that the fee has been paid or a fee waiver request with documentation justifying the waiver.
- Most applications pending at the time of the effective date for covered pesticide actions may voluntarily pay fee

# Schedule of Covered Applications and their Service Fees

- 30 days after effective date (90 days after the bill is signed) schedule of covered pesticide actions, their corresponding fees and timeframes must be published in the FR

# Resubmission of a Covered Pesticide Application

- Establishes criteria under which a resubmission of a pesticide registration application does not need to be accompanied by a new registration service fee

# Fee Adjustment

- While there is no COLA provision in the fees bill, there is a one time, across-the-board 5% increase in fees effective October 1, 2005

# Waivers

- Waivers must include appropriate documentation
- Decisions on waivers must be made within 60 days of their receipt
- Fees for IR-4 submissions are waived
- Other minor use submissions may request a waiver on basis that anticipated revenues not adequate to justify costs

## Waivers: Small Businesses

- If applicant provides adequate documentation demonstrating that it qualifies as a small business, 50% of fee is waived
- If applicant provides adequate documentation demonstrating that it qualifies as a small business **and** demonstrates that average annual gross global revenues < \$10M, then 100% of fee is waived



## Waivers: Federal & State Exemptions

- State and Federal agencies are exempt from the payment of fees



# Refunds

- If application is withdrawn within 60 days after receipt date, then 90% of fee refunded
- If application withdrawn more than 60 days after receipt date, then refund based on percentage of work completed
- Determination of the amount of the refund must be made within 90 days after the date of the withdrawal

## Discretionary Refunds

- Administrator may provide a refund if (1) a significant amount of work was completed on the application prior to the effective date or (2) data submitted in support of another application has been considered

# Pesticide Registration Fund

- Fees from fund used to pay for costs associated with the review of covered pesticide actions
- \$750,000 - \$1.0M per year earmarked for worker protection activities
- \$500,000 in FY04 & FY05 earmarked for review of new inert ingredients

## Authority to assess fees

- Authority to assess fees is suspended if Congressional appropriations and/or Administrator allocations of funds to OPP falls below the amount allocated to OPP in FY02 by more than 3%
- This protection applies for FY04 – FY06

# Decision Time Review Periods

- Timeframes are reduced over the 5 years
- Higher initial timeframes reflect need to “gear up” and address potential backlogs
- Lower timeframes in last two years reflect achievable goals given additional resources and elimination of backlogs

# Decision Time Review Periods

- Covered pesticide applications submitted on or after the effective date are subject to the decision timeframes
- All pending new AI applications are subject to the decision timeframes
- All pending applications that voluntarily pay the fees are subject to the decision timeframes
- By mutual agreement of the Agency and the applicant, the decision time review period can be extended

# Start of the Decision Time Review Period

- Decision time review period begins 21 days after receipt date for applications received on or after March 23, 2004 or when EPA receives the fee payment, whichever is later
- For pending actions where registrant pays fee, the decision time review period begins upon receipt of documentation certifying that payment has been made
- For pending new active ingredients included on RD's FY03 Workplan, the decision time review period begins 30 days after the effective date



# Start of the Decision Time Review Period

- Where the applicant seeks a fee waiver and the Agency grants the waiver, the decision time review period begins no later than 60 days after the receipt date
- For applications where the waiver is denied, the decision time review period begins on the date on which the Agency receives certification that the applicable payment has been made

# Judicial Review

- Covers only new AIs & new uses and only those for which a fee has been paid
- Can only be requested 2 years after the decision review period has expired
- Registrant must request a meeting with the Agency to try to work out the problem 120 days prior to petitioning for judicial review
- The Agency cannot be required or permitted to refund any portion of the fee in response to a complaint to the Administrator

# Accounting & Auditing

- Annual audit report detailing
  - (a) amount of fees received
  - (b) expenditures from the fund
  - (c) decision making performance achieved in comparison with decision completion time periods
  - (d) reasonableness of overhead costs

# Personnel

- FTEs supported out of the fees Fund do not count against agency-wide personnel level caps

# Reports

- # of applications reviewed and their individual decision timeframes
- # of actions pending in each covered category including new inert petitions
- Progress made in meeting timeline requirements
- Description of staffing and resource allocations to support decision-making for covered actions

# Reports

- Actions taken to improve efficiency & cost effectiveness of the registration program
  - Expansion of self-certification
  - Accreditation of outside reviewers
  - Broadening the scope of the notifications process

## Phase Out

- If legislation is not renewed after FY08, a 2 year phase out period kicks in to allow OPP to glide back down to lower FTE levels
- In FY09, the first year of the phaseout, fees are reduced by 40% from FY08 levels
- In FY10, the second year of the phaseout, fees are reduced by 70% from FY08 levels

## Effective Date

- The Effective Date referenced in this legislation refers to the date that is 60 days after the date of enactment
- The Effective Date is March 23, 2004